

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS**

NATIONAL INFUSION CENTER  
ASSOCIATION, on behalf of itself and its  
members; GLOBAL COLON CANCER  
ASSOCIATION, on behalf of itself and its  
members; and PHARMACEUTICAL  
RESEARCH AND MANUFACTURERS OF  
AMERICA, on behalf of itself and its  
members,

Plaintiffs,

vs.

XAVIER BECERRA, in his official capacity  
as Secretary of the U.S. Department of Health  
and Human Services; the U.S.  
DEPARTMENT OF HEALTH AND  
HUMAN SERVICES; CHIQUITA BROOKS-  
LASURE, in her official capacity as  
Administrator of the Centers for Medicare and  
Medicaid Services; and the CENTERS FOR  
MEDICARE AND MEDICAID SERVICES,

Defendants.

Civil Action No. 1:23-cv-00707

**PLAINTIFFS' OPPOSITION TO THE GOVERNMENT'S MOTION TO VACATE  
SCHEDULING ORDER**

This Court should reject the Government’s eleventh-hour attempt to unravel the scheduling order for which they moved and which this Court approved. After weeks of conferring, the parties jointly presented a carefully negotiated scheduling order to expedite resolution of this dispute. Now, after Plaintiffs have submitted their summary judgment brief and accompanying evidence, the Government belatedly asks the Court to suspend summary judgment briefing to first resolve its motion to dismiss—the prospect of which the Government never raised during the parties’ extensive conferrals or preparation of the joint motion to establish the scheduling order. Because the Government fails to satisfy any of the factors for establishing good cause to disturb the scheduling order, and because doing so would significantly prejudice Plaintiffs, the Court should deny the Government’s Motion to Vacate (ECF No. 40) and strike or deny the Government’s motion to dismiss (ECF No. 39) without prejudice to the Government incorporating the same arguments into its cross-motion for summary judgment under the existing schedule. In short, this case should continue under the schedule agreed to by the parties and ordered by this Court.

In light of Plaintiffs’ impending deadline to respond to the Government’s motion to dismiss by September 11, and to avoid rendering moot Plaintiffs’ opposition here, Plaintiffs respectfully request that the Court expeditiously resolve the Government’s Motion to Vacate.<sup>1</sup>

### **BACKGROUND**

Plaintiffs filed their Complaint on June 21, 2023. ECF No. 1. Plaintiffs reached out to the Government by email on July 11 to discuss the briefing schedule. Declaration of Jeffrey Handwerker (Handwerker Decl.) Ex. A, at 9. On July 17, the parties held a call to discuss case scheduling. Handwerker Decl. ¶ 3. During that call, Plaintiffs explained the need to expedite the

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<sup>1</sup> In the alternative, the Court could stay Plaintiffs’ deadline to respond to the Government’s motion to dismiss pending resolution of the Motion to Vacate.

case schedule given the impending deadlines under the Inflation Reduction Act (IRA) for the Government to select which drugs would be part of the first round of “negotiations.” *Id.* ¶ 4. Plaintiffs suggested that, to avoid the need to seek a preliminary injunction or other extraordinary relief, the parties could move directly to cross-motions for summary judgment, as the Government had agreed to in other recently filed lawsuits challenging the IRA. *See, e.g.,* Joint Motion to Set Briefing Schedule and for Other Relief, *Merck & Co. v. Becerra*, No. 1:23-01615 (D.D.C. June 26, 2023); Stipulation and Proposed Order, *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-03335 (D.N.J. July 12, 2023).

The Government agreed that the parties should proceed directly to cross-motions for summary judgment. Handwerker Decl. ¶ 6. However, the Government requested additional time to evaluate Plaintiffs’ proposal, *id.*, which Plaintiffs provided in writing the next day, July 18, *id.* Ex. A, at 7. At no time during this discussion did the Government raise the prospect of filing a motion to dismiss. Handwerker Decl. ¶ 8.

On July 21, the Government emailed Plaintiffs to say that it was continuing to evaluate Plaintiffs’ proposal and that it hoped to have a response soon. *Id.* Ex. A, at 7. On July 28, following an additional inquiry from Plaintiffs, the Government reaffirmed its agreement to a briefing schedule for cross-motions for summary judgment. *Id.* at 4–6. The Government suggested only minor revisions to the proposed schedule to afford the Government additional time to file its combined opposition and cross-motion. *Id.* The Government also affirmed that it “share[d] [Plaintiffs’] desire to get this all resolved as soon as we can.” *Id.* at 3. The Government still did not suggest that it anticipated filing a motion to dismiss. *Id.*

After additional exchanges discussing page limits, *id.* at 1–4, Plaintiffs sent the Government a revised draft joint motion to set the briefing schedule and to dispense with the

Government's obligation to answer the complaint, which the Government approved by email, Handwerker Decl. ¶ 9 & Ex. B, at 1. Plaintiffs filed the joint motion, ECF No. 33, and on August 2, this Court granted the motion and set the current scheduling order, ECF No. 34. Based on the court-ordered schedule, Plaintiffs timely moved for summary judgment on August 10. ECF No. 35.

### ARGUMENT

No good cause exists to vacate the scheduling order. The Government had nearly six weeks from when the Complaint was filed until it agreed to jointly move the Court to enter the current scheduling order. Allowing the Government now to renege on that agreement and undo the current schedule will unnecessarily delay resolution of this dispute and severely prejudice Plaintiffs. The Court should deny the Government's Motion to Vacate.

A court may modify a scheduling order "only for good cause." Fed. R. Civ. P. 16(b)(4); *S&W Enters., L.L.C. v. SouthTrust Bank of Alabama, NA*, 315 F.3d 533, 535 (5th Cir. 2003). The good-cause standard "requires the party seeking relief to show that the deadlines cannot reasonably be met" despite the party's diligence. *Ogden v. Cozumel, Inc.*, No. A-18-CV-00358-DAE-SH, 2019 WL 5080370, at \*1 (W.D. Tex. Oct. 10, 2019) (quotation marks omitted) (rejecting plaintiffs' request to modify scheduling order to file new motion). This standard applies "any time a party seeks to modify a court-imposed schedule." *United States v. 89.9270303 Bitcoins*, No. SA-18-CV-0998-JKP, 2021 WL 9870370, at \*1 (W.D. Tex. Oct. 7, 2021). In assessing good cause, courts consider: "(1) the explanation for the [proposed change to] the scheduling order; (2) the importance of the modification; (3) potential prejudice in allowing the modification; and (4) the availability of a continuance to cure such prejudice." *Springboards To Educ., Inc. v. Houston Indep. Sch. Dist.*,

912 F.3d 805, 819 (5th Cir. 2019) (brackets omitted) (affirming district court’s refusal to modify summary judgment briefing schedule).

The Government does not cite the applicable standard governing its Motion to Vacate, and the motion fails to establish the requisite good cause. Indeed, all four factors weigh against it.

*First*, vacating the scheduling order is inappropriate where, as here, the Government “made an intentional decision not to file the motion” weeks ago. *Ogden*, 2019 WL 5080370, at \*2. The Government had ample time and opportunity to decide whether to move to dismiss *before* it ultimately agreed to proceed directly to motions for summary judgment. After multiple conferrals spanning several weeks, the parties agreed that this case is best suited to resolution on cross-motions for summary judgment. ECF No. 33. The Government had the Complaint for nearly a month before it began discussing a potential scheduling order with Plaintiffs. Then, after hearing Plaintiffs’ proposal for a schedule limited to cross-motions for summary judgment, the Government sought an additional two weeks to decide whether to agree—no doubt weighing the potential risks and benefits of that approach, including the possibility of filing a motion to dismiss. Yet the Government never proposed including deadlines in the scheduling order related to a potential forthcoming motion to dismiss. Indeed, the parties agreed that the Court should dispense with the Government’s obligation to answer the complaint.

Now, nearly a month after this Court entered its scheduling order and three weeks after Plaintiffs moved for summary judgment, the Government asks the Court for a mulligan. But “[g]ood cause does not typically include a change of heart on a litigation strategy.” *FCCI Ins. Co. v. DS Mech. Contractors, Inc.*, No. EP-16-CV-495-PRM, 2017 WL 11218982, at \*5 (W.D. Tex. July 25, 2017) (quoting *Martinez v. Petrenko*, 792 F.3d 173, 180 (1st Cir. 2015)). Absent a significant change of circumstances—which did not occur here—the Government’s decision to

jointly move the Court for a specific briefing schedule constitutes an affirmative waiver of its right to seek vacatur of that schedule.

*R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Administration*, No. 6:20-CV-00176, 2022 WL 17489170 (E.D. Tex. Dec. 7, 2022), is instructive. There, as here, the Government and private plaintiffs jointly agreed to move directly to cross-motions for summary judgment to resolve a dispute over a pure legal question (there, labeling requirements under an FDA rule). *Id.* at \*10. In addition to filing its motion for summary judgment, however, the Government separately moved to dismiss for improper venue. *Id.* at \*8. Considering the venue and merits issues together, the court emphasized that the Government “first objected to venue over 12 weeks after service of the complaint and over 8 weeks after it stipulated to a court order staying the [FDA] rule’s effectiveness.” *Id.* at \*11. And because the Government “had ample time and resources to assess venue before it joined plaintiffs in moving to postpone the rule’s effectiveness and proposing that the court move directly to cross-motions for summary judgment,” the court held that “the government’s venue defense [wa]s waived.” *Id.* at \*10–11. The same analysis applies here. The Government had ample time to assess venue before it jointly moved for a schedule proceeding directly to cross-motions for summary judgment. The Government has waived its right to raise a venue defense outside of the schedule it agreed to and successfully urged this Court to adopt.

The Government attempts to justify its change of heart based on the notion (at 5) that it “did not become aware of the full scope of the venue problem until recently, after Plaintiffs filed their summary-judgment papers.” That assertion is belied by the Government’s own motion to dismiss. ECF No. 39. That motion turns primarily on the Government’s argument that NICA lacks *standing*, which the Government acknowledges “is to be assessed under the facts *existing when the complaint is filed*.” *Id.* at 16 (emphasis added). Indeed, the motion to dismiss relies on alleged

pleading deficiencies in the complaint—with only a few perfunctory add-on references to Plaintiffs’ summary judgment papers. *See, e.g., id.* at 8 (“Plaintiffs’ complaint does not identify a single member of NICA (nor does Plaintiffs’ summary-judgment motion)”); *id.* at 9 (noting “several factual allegations” missing from the *Complaint* purportedly necessary to establish standing); *id.* at 13 (“[N]one of these channeling principles are addressed in the complaint (or in Plaintiffs’ summary-judgment motion).”). In short, the Government had the opportunity to assess venue and potential challenges thereto, including a potential motion to dismiss, before it asked the court to enter the current schedule. *See Reliance Ins. Co. v. Louisiana Land & Expl. Co.*, 110 F.3d 253, 258 (5th Cir. 1997) (“District judges have the power to control their dockets by refusing to give ineffective litigants a second chance to develop their case.”). Having failed to do so, the Government should not now be heard to complain about the scheduling order it sought. Whatever problems the Government claims the scheduling order may cause are the result of the Government’s own choices.<sup>2</sup>

*Second*, the Government offers no “important” reason to suspend the schedule. *Springboards*, 912 F.3d at 819. The Government asserts that suspending the schedule is necessary for two reasons: to comply with the Fifth Circuit’s “direction” to give ““top priority”” to disposition of a venue-related motion, and to promote “the interest of efficiency.” ECF No. 40 at 3 (quoting *In re Horseshoe Ent.*, 337 F.3d 429, 433 (5th Cir. 2003)). Neither reason makes sense.

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<sup>2</sup> For similar reasons, the Government’s claim (at 5 n.2) that it “timely filed their Motion to Dismiss by the deadline to answer or otherwise respond to the complaint” is misplaced. As an initial matter, based on the negotiated briefing schedule, the parties agreed that the Government need not file an answer. The Government thus had no “deadline to answer or otherwise respond to the complaint” to meet. Regardless, the Government’s motion to dismiss was untimely in that it was not filed until *after* the parties agreed on a schedule; *after* the parties jointly moved the Court for a scheduling order; *after* the Court entered the scheduling order; and *after* Plaintiffs moved for summary judgment and disclosed their accompanying evidence. *See infra* pp. 8–9.

The need to give “top priority” to venue arguments does not justify suspending the schedule. Nothing precludes the Government from incorporating its venue (and other non-merits) arguments into its cross-motion for summary judgment. *See, e.g., R.J. Reynolds Tobacco Co.*, 2022 WL 17489170, at \*11 (resolving government’s motion to dismiss based on improper venue along with the parties’ cross-motions for summary judgment); *Gutierrez v. Drill Cuttings Disposal Co., L.L.C.*, 319 F. Supp. 3d 856, 858–59 (W.D. Tex. 2018) (resolving motion for summary judgment before considering venue challenge). None of the cases the Government cites discourages—much less bars—a court from considering threshold arguments in conjunction with merits briefing, especially when the court has previously entered a briefing schedule to which the parties agreed.<sup>3</sup> The Government did not make a “priority” of venue arguments in proposing a schedule; there is no basis for relieving two high-ranking Government officials and the two federal agencies they lead—“a group of uncommonly sophisticated and well-represented litigants”—of that choice. ECF No. 39 at 18.

Nor would suspending the briefing schedule serve “the interest of efficiency.” Indeed, the Government’s citation to efficiency gets things backwards: *granting* the Government’s motion would create inefficiencies. To start, Plaintiffs have already submitted their motion for summary judgment, along with *six* declarations. Allowing the Government to avoid its obligation to respond risks wasting Plaintiffs’ time, effort, and expense. The Government has nothing to say about that.

The Government repeatedly argues (at 3, 4) that *if* the Court grants its motion to dismiss, it would preserve judicial resources because the Court will not need to address the merits of the dispute. But as explained, the Government can pursue its standing, venue, and other threshold

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<sup>3</sup> Indeed, many of the Government’s cited cases involve *motions to transfer*, largely in patent actions. *See* ECF No. 40 at 3 (citing, *e.g., In re Apple Inc.*, 979 F.3d 1332, 1337 (Fed. Cir. 2020), and substituting “a [venue-related motion]” where the court used “transfer motion”).



arguments in its forthcoming cross-motion for summary judgment. Accordingly, the Court can still just as easily preserve judicial resources by resolving those threshold issues first, if it so chooses. And if the Court *rejects* the Government's standing and venue arguments,<sup>4</sup> then the Court can turn expeditiously to the merits of Plaintiffs' claims, which will already have been briefed. For similar reasons, in conjunction with denying the Government's Motion to Vacate, the Court could strike or deny the Government's motion to dismiss without prejudice to incorporating the same arguments into its cross-motion for summary judgment under the existing schedule. Proceeding in either manner also avoids the inefficiencies in the Government's proposal (at 4) that the Court should set a *new* briefing schedule if it denies the Government's motion to dismiss. The Government's proposed schedule promotes efficiency *only* for the Government, and it can hardly be heard to complain about inefficiencies caused by its own litigation choices.

*Third*, granting the Government's motion will substantially prejudice Plaintiffs in multiple respects.

From the first discussion with the Government, Plaintiffs made clear that a swift resolution of the case was of paramount concern given impending statutory deadlines. Plaintiffs discussed the possibility of seeking a preliminary injunction, but agreed that could be avoided if the Government consented to an expedited schedule for resolving the case on cross-motions for summary judgment. Now, nearly 10 weeks after the complaint was filed and 4 weeks after the

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<sup>4</sup> The Government's standing argument lacks merit. The IRA's maximum fair price requirements, among other things, will adversely affect NICA member reimbursement for many products that they regularly administer and prescribe, including certain products that now appear on the initial list of drugs selected for negotiation that CMS published on August 29, 2023. As Plaintiffs will explain in more detail in their forthcoming opposition to the Government's standing and channeling arguments, NICA members are injured in fact by the IRA's maximum fair price requirements, and NICA has associational standing to bring the claims set out in the Complaint on their behalf.

parties agreed on a joint schedule, the Government wants to renege on that bargain after Plaintiffs acted in reliance on it to their detriment by not seeking preliminary relief.

Granting the Government's motion will also prejudice Plaintiffs by giving the Government an unfair litigation-related advantage. Plaintiffs filed their motion for summary judgment on August 10, consistent with their obligation under the scheduling order. ECF No. 35. In support of that filing, Plaintiffs submitted six declarations, including a declaration from their expert. *Id.* Plaintiffs never would have disclosed that evidence had they known that the Government intended to file a motion to dismiss. Relieving the Government of its obligation to respond under the scheduling order would give it a significant unfair advantage by vastly extending its time to respond. If the Court grants the Government's Motion to Vacate, it will in effect double or triple the time the Government otherwise would have had to respond to Plaintiffs' motion for summary judgment. Simply put, there is no merit to the Government's assertion (at 4) that Plaintiffs' "litigation choices . . . indicate that they are unlikely to be prejudiced by a temporary deferral of the summary-judgment briefing deadlines."

*Fourth*, a continuance would not cure the prejudice of Plaintiffs forgoing a motion for a preliminary injunction, giving the Government early access to Plaintiffs' evidence, and vastly expanding the Government's time to respond to Plaintiffs' summary judgment motion. The issue is not that the Government's proposed motion will disturb later case deadlines, but rather that the Government will have gained an unfair advantage in multiple ways.

Because the Government offers no reason to disturb the current scheduling order, its Motion to Vacate should be denied in full. As an alternative, however, the Court could set a briefing schedule in which the parties brief the motion to dismiss in conjunction with the summary judgment schedule, as another court overseeing an IRA case has done. *See* Agreed Order Setting

Briefing Schedule, *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-00156 (S.D. Ohio July 27, 2023) (ordering that motion to dismiss must be briefed in tandem with preliminary-injunction briefing). Under that framework, the briefing would proceed as follows:

- The Government files its combined cross-motion for summary judgment and opposition to Plaintiffs' motion for summary judgment by September 29, 2023.
- Plaintiffs file a combined reply in support of their motion and opposition to the Government's cross-motion, as well as a separate opposition to the Government's motion to dismiss, by October 26, 2023.
- The Government files a reply in support of its cross-motion, and a separate reply in support of its motion to dismiss, by November 17, 2023.

To be clear, because the Government has wholly failed to establish good cause to modify the scheduling order, the Court should deny the Government's Motion to Vacate. But Plaintiffs suggest the compromise above as a potential option to mitigate the extreme prejudice they would otherwise suffer.

### CONCLUSION

For the foregoing reasons, the Court should deny the Government's Motion to Vacate. Plaintiffs respectfully suggest that the Court should strike or deny the Government's motion to dismiss without prejudice to the Government incorporating the same arguments into its cross-motion for summary judgment under the existing schedule; in the alternative, the Court could set a briefing schedule in which the parties brief the motion to dismiss in conjunction with the existing summary judgment schedule, as detailed above. Plaintiffs further request that the Court expedite its resolution of the Motion to Vacate or stay Plaintiffs' deadline to respond to the Government's motion to dismiss pending resolution of the Motion to Vacate.

DATED: August 31, 2023

/s/ Michael Kolber

Michael Kolber

Respectfully submitted,

/s/ Tim Cleveland

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